

NATIONAL



AUTHORITY

20<sup>th</sup> February 2024

Ref: 0335G/DR/NDA-02/2024

To: Marketing Authorization Holders  
Pharmacies  
Local Technical Representatives

**CIRCULAR NO. 003/DPAR/2024**

**WITHDRAWAL OF MARKETING AUTHORISATION FOR KETOCONAZOLE ORAL TABLETS**

The above subject refers.

Ketoconazole is a synthetic broad-spectrum antifungal agent that was first marketed by Janssen Pharmaceuticals (Belgium) under the brand name 'Nizoral'. The risk of liver injury resulting from the use of oral Ketoconazole has received considerable attention worldwide.

The Authority concluded that the benefit – risk balance of oral Ketoconazole was negative because of high level of liver injury associated with medicine and in view of the currently available alternative treatment, which are deemed safer. Oral ketoconazole is however also used in the treatment of Cushing's syndrome; and it has a positive benefit-risk balance for this indication, as there might not be satisfactory alternative treatments.

In light of the above, the authority resolved as follows:

- To withdraw of the Marketing Authorisation for all oral Ketoconazole products, with immediate effect.
- To ensure continued access of patients with Cushing's syndrome to oral Ketoconazole, the medicine shall only be imported as special importations

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To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

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## CONTINUATION SHEET

strictly for Cushing's syndrome patients upon prescription by an appropriate specialist.

- c) Topical formulations of ketoconazole (such as creams, ointments and shampoos) continue to be used as the amount of Ketoconazole absorbed throughout the body is very low with these formulations.

Yours faithfully,

  
David Nahamya  
SECRETARY TO THE AUTHORITY



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